In re of: ORNTOFT et al.

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1.   (Original) A method of predicting the prognosis of a biological condition in animal tissue,

comprising collecting a sample comprising cells from the tissue and/or expression products from the cells,

determining an expression level of at least one gene in the sample, said gene being selected from the group of genes consisting of gene No. 1 to gene No. 562,

correlating the expression level to at least one standard expression level to predict the prognosis of the biological condition in the animal tissue.

2.   (Original) The method of claim 1, wherein the animal tissue is selected from body organs.

3.   (Original) The method of claim 2, wherein the animal tissue is selected from epithelial tissue in body organs.

4.   (Original) The method of claim 3, wherein the animal tissue is selected from epithelial tissue in the urinary bladder.

5.   (Currently Amended) The method ~~according to~~ of claim 4, wherein the stage <u>of the biological condition</u> is selected from bladder cancer stages Ta, Carcinoma in situ (CIS), T1, T2, T3 and T4.

6.   (Currently Amended) The method ~~according to~~ of claim 5, comprising determining at least the expression of a Ta stage gene from a Ta stage gene group, at least one T1 stage gene from a T1 stage gene group, at least a T2 stage gene from a T2 stage gene group, at least a T3 stage gene from a T3 stage gene group, at least a T4 stage gene group from a T4 stage gene group, wherein at least one gene from each gene group is expressed in a significantly different amount in that stage than in one of the other stages.

7.   (Currently Amended) The method ~~according to~~ of claim ~~4,~~ 5 ~~or 6~~, wherein the stage is bladder cancer stage Ta.

8.   (Currently Amended) The method ~~according to~~ of claim 4, wherein the animal tissue is mucosa.

9.   (Currently Amended) The method of ~~any of the preceding claims~~<u>claim 1</u>, wherein the biological condition is an adenocarcinoma, a carcinoma, a teratoma, a sarcoma, and/or a lymphoma and/or carcinoma-in-situ, and/or dysplasia-in-situ.

10.   (Currently Amended) The method of ~~any of the preceding claims~~claim 1, wherein the sample is a biopsy of the tissue or of metastasis originating from said tissue.

11.   (Cancelled)

12.   (Currently Amended) The method ~~according to any of the preceding claims~~of claim 1, wherein the sample comprises substantially only cells from said tissue.

13.   (Original) The method according to claim 9, wherein the sample comprises substantially only cells from mucosa or tumors derived from said mucosa cells.

14.   (Currently Amended) The method ~~according to any of the preceding claims~~of claim 1, wherein the gene from the group of genes is selected individually from the group consisting of gene No. 1 to gene No. 188 (stages).

15.   (Currently Amended) The method ~~according to any of the preceding claims 1-13~~of claim 1, wherein the gene from the group of genes is selected individually from the group consisting of gene No. 189 to gene No. 214 (recurrence).

16.   (Currently Amended) The method ~~according to any of the preceding claims 1-13~~of claim 1, wherein the gene from the group of genes is selected individually from the group consisting of gene No. 215 to gene No. 232 (SCC).

17.   (Currently Amended) The method ~~according to any of the preceding claims 1-13~~of claim 1, wherein the gene from

the group of genes is selected individually from <u>the group</u> <u>consisting of</u> gene No. 233 to gene No. 446 (progression).

18.   (Currently Amended) The method ~~according to any~~ ~~of the preceding claims 1-13~~<u>of claim 1</u>, wherein the gene from the group of genes is selected individually from <u>the group</u> <u>consisting of</u> gene No. 447 to gene No. 562 (CIS).

19.   (Currently Amended) The method ~~according to any~~ ~~of the preceding claims~~<u>of claim 1</u>, wherein the expression level of at least two genes from the group of genes are determined.

20.   (Currently Amended) The method ~~according to any~~ ~~of the preceding claims~~<u>of claim 1</u>, wherein the expression level of at least three genes from the group of genes are determined.

21.- 23.   (Cancelled)

24.   (Currently Amended) The method ~~according to any~~ ~~of the preceding claims~~<u>of claim 1</u>, wherein the difference in expression level of a gene from the gene group to the at least one standard expression level is at least two-fold.

25.   (Currently Amended) The method ~~according to any~~ ~~of the preceding claims~~<u>of claim 1</u>, wherein the difference in expression level of a gene from the gene group to the at least one standard expression is at least three-fold.

26.   (Currently Amended) The method ~~according to any~~ ~~of the preceding claims~~<u>of claim 1</u>, wherein the difference in

expression level of a gene from the gene group to the at least one standard expression is at least four-fold.

27. (Currently Amended) The method ~~according to any of the preceding claims~~of claim 1, wherein the expression level is determined by determining the mRNA of the cells.

28. (Currently Amended) The method ~~according to any of the claims 1-26~~of claim 1, wherein the expression level is a) determined by determining expression products~~, such as peptides,~~ in the cells, or b) is determined by determining expression products in a body fluid.

29. (Cancelled)

30. (Currently Amended) The method ~~according to any of the preceding claims~~of claim 1, wherein the stage of the biological condition has been determined prior to the prediction of the prognosis.

31. (Currently Amended) The method ~~according to~~ of claim 30, wherein the stage of the biological condition has been determined by histological examination of the tissue or by genotyping of the tissue.

32. (Cancelled)

33. (Currently Amended) The method ~~according to~~ of claim 31~~or 32~~, wherein the stage of the biological condition has been determined by

determining the expression of at least a first stage gene from a first stage gene group and/or at least a second stage gene from a second stage gene group, wherein at least one of said genes is expressed in said first stage of the condition in a higher amount than in said second stage, and the other gene is a expressed in said first stage of the condition in a lower amount than in said second stage of the condition,

correlating the expression level of the assessed genes to a standard level of expression determining the stage of the condition.

34. (Currently Amended) The method ~~according to any of the preceding claims~~of claim 1, wherein the expression level of at least two genes is determined, by

determining a first expression level of at least one gene from a first gene group, wherein the gene from the first gene group is selected from the group consisting of gene No. 237, 238, 239, 240, 241, 242, 243, 245, 246, 247, 248, 250, 253, 254, 257, 258, 260, 263, 264, 265, 267, 270, 271, 272, 278, 283, 284, 287, 288, 290, 291, 292, 294, 297, 298, 300, 302, 303, 305, 309, 310, 315, 316, 317, 318, 319, 321, 324, 329, 335, 336, 337, 339, 340, 344, 346, 347, 354, 356, 358, 359, 362, 364, 365, 368, 369, 371, 372, 377, 378, 379, 380, 381, 382, 383, 384, 388, 391, 393, 395, 396, 397, 399, 402, 403, 404, 409, 413, 417, 419, 420, 421, 422, 423, 425, 427 ,429, 430, 431, 432, 437, and 444 (progressorgener), and

determining a second expression level of at least one gene from a second gene group, wherein the second gene group is selected from the group consisting of genes No. 233, 234, 235,

236, 244, 249, 251, 252, 255, 256, 259, 261, 262, 266, 268, 269, 273, 274, 275, 276, 277, 279, 280, 281, 282, 285, 286, 289, 293, 295, 296, 299, 301, 304, 306, 307, 308, 311, 312, 313, 314 , 320 , 322, 323, 325, 326, 327, 328 , 330, 331, 332, 333, 334, 338, 341, 342, 343, 345, 348, 349, 350, 351, 352, 353, 355, 357, 360, 361, 363, 366, 367, 370, 373, 374, 375, 376, 385, 386, 387, 389, 390, 392, 394, 398, 400, 401, 405, 406, 407, 408, 410, 411, 412, 414, 415, 416, 418, 424, 426, 428, 433, 434, 435, 436, 438, 439, 440, 441, 442, 443, 445, and 446 (non-progressorgener), and

correlating the first expression level to a standard expression level for progressors, and/or the second expression level to a standard expression level for non-progressors to predict the prognosis of the biological condition in the animal tissue.

35.   (Original) A method of determining the stage of a biological condition in animal tissue, comprising collecting a sample comprising cells from the tissue,

determining an expression level of at least one gene selected from the group of genes consisting of gene No 1 to gene No. 562

correlating the expression level of the assessed genes to at least one standard level of expression determining the stage of the condition.

36.   (Currently Amended) The method ~~according to~~ of claim ~~36~~35, wherein the expression level of at least two genes is determined by

determining the expression of at least a first stage gene from a first stage gene group and at least a second stage gene from a second stage gene group, wherein at least one of said genes is expressed in said first stage of the condition in a higher amount than in said second stage, and the other gene is a expressed in said first stage of the condition in a lower amount than in said second stage of the condition, and

correlating the expression level of the assessed genes to a standard level of expression determining the stage of the condition

37. (Currently Amended) The method ~~according to~~ ~~claim~~ of claim 35 ~~or 36~~, wherein the stage is selected from bladder cancer stages Ta, carcinoma in situ (CIS), T1, T2, T3 and T4.

38. (Currently Amended) The method ~~according to~~ of claim 37, comprising determining at least the expression of a Ta stage gene from a Ta stage gene group, at least one T1 stage gene from a T1 stage gene group, at least a T2 stage gene from a T2 stage gene group, at least a T3 stage gene from a T3 stage gene group, or at least a T4 stage gene ~~group~~ from a T4 stage gene group, wherein at least one gene from each gene group is expressed in a significantly different amount in that stage than in one of the other stages.

39. (Currently Amended) The method ~~according to~~ of claim 38, wherein a Ta stage gene is selected individually from the group of Table B1.

In re of: ORNTOFT et al.

40.   (Currently Amended) The method ~~according to~~ of
claim 38, wherein a T1 stage gene is selected individually
from the group of Table B2.

41.   (Currently Amended) The method ~~according to~~ of
claim 38, wherein a T2 stage gene is selected individually
from the group of Table B3.

42.   (Cancelled)

43.   (Original) A method of determining an
expression pattern of a bladder cell sample, comprising:

collecting sample comprising bladder cells and/or expression
products from bladder cells,

determining the expression level of at least one gene in the
sample, said gene being selected from the group of genes
consisting of gene No. 1 to gene No. 562, and obtaining an
expression pattern of the bladder cell sample.

44.   (Currently Amended) The method ~~according to
claim~~ of 43, wherein the expression level of at least two
genes are determined.

45.   (Currently Amended) The method ~~according to
claim~~ of 43, wherein the expression level of at least three
genes are determined.

46. - 48. (Cancelled)

49.   (Currently Amended) The method of claims 43—48, wherein the genes exclude genes which are expressed in the submucosal, muscle, or connective tissue, whereby a pattern of expression is formed for the sample which is independent of the proportion of submucosal, muscle, or connective tissue cells in the sample.

50.   (Original) The method of claim 49, comprising determining the expression level of one or more genes in the sample comprising predominantly submucosal, muscle, and connective tissue cells, obtaining a second pattern, subtracting said second pattern from the expression pattern of the bladder cell sample, forming a third pattern of expression, said third pattern of expression reflecting expression of the bladder mucosa or bladder cancer cells independent of the proportion of submucosal, muscle, and connective tissue cells present in the sample.

51.   (Currently Amended) The method of any of the preceding claims 43-50 claim 43, wherein the sample is a biopsy of the tissue.

52.   (Currently Amended) The method according to any of the preceding claim 43-51 of claim 43, wherein the sample is a cell suspension.

53.   (Currently Amended) The method according to any of the preceding claims 43-52 of claim 43, wherein the sample comprises substantially only cells from said tissue.

54. (Original) The method according to claim 53, wherein the sample comprises substantially only cells from mucosa.

55. (Currently Amended) A method of predicting the prognosis a biological condition in human bladder tissue comprising,

collecting a sample comprising cells from the tissue,

determining an expression pattern ~~of the cells as defined in any of claims 43-54,~~of a bladder cell sample, comprising:

<u>collecting sample comprising bladder cells and/or expression products from bladder cells,</u>

<u>determining the expression level of at least one gene in the sample, said gene being selected from the group of genes consisting of gene No. 1 to gene No. 562, and obtaining an expression pattern of the bladder cell sample,</u>

correlating the determined expression pattern to a reference pattern,

predicting the prognosis of the biological condition of said tissue.

56. (Currently Amended) A method for determining the stage of a biological condition in animal tissue comprising,

collecting a sample comprising cells from the tissue,

In re of: ORNTOFT et al.

determining an expression pattern of ~~the cells as defined in any of claims 43-54,~~a bladder cell sample, comprising:

collecting sample comprising bladder cells and/or expression products from bladder cells,

determining the expression level of at least one gene in the sample, said gene being selected from the group of genes consisting of gene No. 1 to gene No. 562, and obtaining an expression pattern of the bladder cell sample,

correlating the determined expression pattern to a reference pattern,

determining the stage of the biological condition is said tissue.

57. - 71. (Cancelled)

72. (Original) An assay for predicting the prognosis of a biological condition in animal tissue, comprising

at least one first marker capable of detecting an expression level of at least one gene selected from the group of genes consisting of gene No. 1 to gene No. 562.

73. (Original) The assay according to claim 72, wherein the marker is a nucleotide probe.

13

74. (Original) The assay according to claim 72, wherein the marker is an antibody.

75. (Currently Amended) The assay according to claim 72, comprising at least a first marker and/or a second marker, wherein the first marker is capable of detecting a gene from a first gene group ~~as defined in claim 34~~, and/or the second marker is capable of detecting a gene from a second gene group, ~~as defined in claim 34~~ where the gene from the first group is selected from the group consisting of gene No. 237, 238, 239, 240, 241, 242, 243, 245, 246, 247, 248, 250, 253, 254, 257, 258, 260, 263, 264, 265, 267, 270, 271, 272, 278, 283, 284, 287, 288, 290, 291, 292, 294, 297, 298, 300, 302, 303, 305, 309, 310, 315, 316, 317, 318, 319, 321, 324, 329, 335, 336, 337, 339, 340, 344, 346, 347, 354, 356, 358, 359, 362, 364, 365, 368, 369, 371, 372, 377, 378, 379, 380, 381, 382, 383, 384, 388, 391, 393, 395, 396, 397, 399, 402, 403, 404, 409, 413, 417, 419, 420, 421, 422, 423, 425, 427 ,429, 430, 431, 432, 437, and 444 (progressorgener), and

where the gene from the second gene group is selected from the group consisting of genes No. 233, 234, 235, 236, 244, 249, 251, 252, 255, 256, 259, 261, 262, 266, 268, 269, 273, 274, 275, 276, 277, 279, 280, 281, 282, 285, 286, 289, 293, 295, 296, 299, 301, 304, 306, 307, 308, 311, 312, 313, 314 , 320 , 322, 323, 325, 326, 327, 328 , 330, 331, 332, 333, 334, 338, 341, 342, 343, 345, 348, 349, 350, 351, 352, 353, 355, 357, 360, 361, 363, 366, 367, 370, 373, 374, 375, 376, 385, 386, 387, 389, 390, 392, 394, 398, 400, 401, 405, 406, 407, 408, 410, 411, 412, 414, 415, 416, 418, 424, 426, 428, 433, 434, 435, 436, 438, 439, 440, 441, 442, 443, 445, and 446 (non-progressorgener).

76.   (Currently Amended) The assay according to ~~any~~ ~~of~~ claim~~s~~ 72~~-75~~, said assay further comprising means for correlating the expression level of the at least one gene to a standard expression level and/or a reference expression pattern.